



DEPARTMENT OF HEALTH & HUMAN SERVICES

m3184n

New York District

Food & Drug Administration  
850 Third Avenue  
Brooklyn, NY 11232

**WARNING LETTER**

November 2, 1999

REF: NYK-2000-07

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Kumudha Ramanathan, M.D.  
U.C. Medical Diagnostic Services, P.C.  
2187 Ocean Avenue  
Brooklyn, New York 11229

Facility ID: 169342

Dear Dr. Ramanathan:

Your facility was inspected on October 14, 1999 by a representative of this agency. This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 finding at your facility:

*The medical physicist, [REDACTED], did not have a Bachelors degree in a physical science, with 10 semester hours or more in physics prior to April 28, 1999.*

The specific problem noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. This problem is identified as Level 1 because it identifies a failure to meet significant MQSA requirements.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

U.C. Medical Diagnostic Services, P.C.  
Warning Letter NYK-2000-07

In addition, your response should address the Level 2 finding that were listed on the inspection report provided at the close of the inspection. The Level 2 findings are:

1. [REDACTED] *did not meet the requirement of conducting surveys for at least one facility and 20 units before April 28, 1999, and after the Bachelors degree; and*
2. [REDACTED] *also failed to meet the requirement of having a minimum of 40 contact hours of training in conducting surveys before April 28, 1999, and after the Bachelors degree.*

It is necessary for you to act on these matters immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

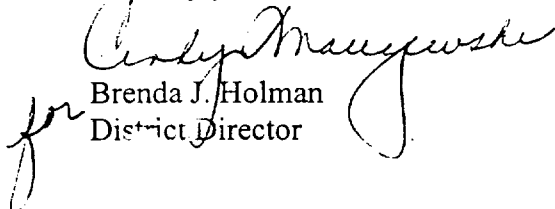
- The specific steps you have taken to correct the violation noted in this letter;
- Each step your facility is taking to prevent the recurrence of a similar violation;

Please submit your response to the attention of Lillian C. Aveta, Compliance Officer, U.S. Food and Drug Administration, 850 Third Avenue, Brooklyn, New York 11232, Tel. (718) 340-7000, ext. 5142.

Finally, you should understand there are many FDA requirements pertaining to mammography. This letter pertains only to findings of our inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, Maryland 21045-6057 (1-800-838-7715), or through the Internet at <http://www.fda.gov>.

If you have any questions about mammography facility requirements in general, please feel free to contact Murray L. Kurzman, Radiation Programs Manager, at (516) 921-2035.

Sincerely yours,

  
for Brenda J. Holman  
District Director